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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/109,864 07/06/98 NI J PF354P1

022195 HM12/1102
HUMAN GENOME SCIENCES INC
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ROCKVILLE MD 20850

EXAMINER

ULM, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

11/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/109,864

Applicant(s)
Ni et al.

Examiner
John Ulm

Group Art Unit
1646



☒ Responsive to communication(s) filed on Aug 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 29-41, 43-93, 95, and 105-153 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 29-41, 43-93, 95, and 105-153 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1) Claims 29 to 41, 43 to 93, 95 and 105 to 153 are pending in the instant application. Claims 35, 39 to 41, 44, 53, 66, 68, 70 to 73, 75 to 77, 79, 82 to 87 and 91 to 93 have been amended, claims 42, 94 and 96 to 105 have been canceled and claims 106 to 153 have been added as requested by Applicant in Paper Number 14, filed 17 August of 2000.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claim 73 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A dependant claim can not depend from part of a previous claims..

5) Claim 44 is objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

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The amino acid sequences recited in this claim do not share a substantial structural feature which is disclosed as a basis for a common utility.

6) This application contains claims directed to the patentably distinct species of amino acid sequence as listed in claim 44 .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 29 to 41, 43 to 93, 95 and 105 to 153 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein identified therein as "galectin 11" and the protein encoded thereby. The instant application alleges that "galectin 11" is a carbohydrate binding protein, but provides no functional evidence that the disclosed protein actually binds to any carbohydrate. The identification of "galectin 11" as a lectin appears to be based upon the fact that the most closely related protein in the prior art is a rat protein known as "galectin 5". However, because the amino acid sequence of "galectin 11", as presented in SEQ ID NO:2 of the instant application, is less than 18% identical to the amino acid sequence of "galectin 5". A reasonable artisan of molecular biology would not reasonably conclude that two proteins which differ in amino acid sequence by more than 80% would share a common function, in the absence of experimental evidence demonstrating this common function.

It is clear from the instant specification that the receptor protein described therein as "galectin 11" is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its apparent similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible

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utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion the a protein of the instant invention is associated in any way with the plurality of causally unrelated disorders that are listed on page 33 of the instant specification. Until some actual and specific significance can be attributed to the protein identified in the specification as "galectin 11", or the gene encoding it, the instant invention is incomplete. The

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protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as galectins. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for "galectin 11" then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

8) Claims 29 to 41, 43 to 93, 95 and 105 to 153 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

9) Claims 111, 126, 136 and 145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9.1) Claims 111 and 126 are indefinite because there is no "(e)" in the claims from which each of these claims depend.

9.2) Claims 136 and 145 are vague and indefinite because there is no antecedent basis for "a polypeptide encoded by". These claims should refer to "a polypeptide comprising" (or "having") "the amino acid sequence encoded by".

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10) Applicant's arguments filed 17 August of 2000 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800